UNITED STATES DISTRICT COURT DISTRICT OF MAINE

PUTNEY, INC.,)
Plaintiff,)
v.	Civil Docket No. 2:07-cv-00108-DBH
PFIZER INC. and MWI VETERINARY SUPPLY, INC.,) JURY TRIAL DEMANDED
Defendants.)

FIRST AMENDED COMPLAINT FOR DAMAGES, DECLARATORY JUDGMENT, AND INJUNCTIVE RELIEF

Plaintiff, Putney, Inc. (hereinafter "Putney"), by and through its undersigned counsel, hereby makes this First Amended Complaint against Defendants Pfizer Inc. ("Pfizer") and MWI Veterinary Supply, Inc. ("MWI") (together, "Defendants"), in support of which Putney states as follows:

Parties and Jurisdiction

- 1. Putney is a Delaware corporation with a principal place of business located at 120 Exchange Street, Portland, Maine 04101.
- 2. On information and belief, Pfizer is a Delaware corporation with its world headquarters located at 235 East 42nd Street, New York, New York 10017.
- 3. MWI is a Delaware corporation with a principal place of business located at 651S. Statford Drive, Suite 100, Meridian, Idaho 83642.
- 4. This action arises under, *inter alia*, the Lanham Act, 15 U.S.C. § 1051 *et seq.*; the Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA"), Pub. L. No. 103-396,

1994 U.S.C.C.A.N. 4153 (codified at 21 U.S.C. § 360(b)); the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the common law and statutory law of the State of Maine.

- 5. The Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1337. This Court has supplemental jurisdiction over Putney's state law claims under 28 U.S.C. § 1367.
- 6. This Court has personal jurisdiction over the Defendants because they conduct substantial business in, and have regular and systematic contact with, this District; because they have purposefully availed themselves of the privileges of conducting activities within this District; and because the unlawful conduct complained of herein was committed against, and has harmed and damaged, a party located in this District.
 - 7. Venue is proper in this District under 28 U.S.C. § 1391(c).

Factual Background

The parties

- 8. Putney is engaged in the business of selling pharmaceutical products for veterinary use in accordance with AMDUCA and developing, licensing and obtaining approval of the United States Food and Drug Administration's ("FDA") Center for Veterinary Medicine to sell bioequivalent generic drugs for companion animals.
- 9. MWI is engaged in the business of selling and distributing pharmaceutical products, including FDA human and animal approved products, to the veterinary community.
- 10. On information and belief, Pfizer is the world's largest manufacturer and seller of human pharmaceuticals and the world's largest manufacturer and seller of veterinary pharmaceuticals.

11. Upon information and belief, MWI has a business relationship with Pfizer regarding veterinary products, including pharmaceuticals for veterinary use.

Cefpodoxime proxetil

- 12. Cefpodoxime proxetil is an anti-infective.
- 13. Pfizer purportedly holds market exclusivity for the veterinary-approved product Simplicef[®] (cefpodoxime proxetil), which exclusivity, upon information and belief, expires on July 22, 2009.
- 14. According to the product labeling, FDA approved Simplicef[®] (cefpodoxime proxetil) tablets, 100 mg and 200 mg, for use "the treatment of skin infections (wounds and abscesses) in dogs" caused by susceptible strains of the designated microorganisms.
- 15. On information and belief, Pfizer obtained FDA approval for its Simplicef[®] products in or about July 2004, and began marketing these products to veterinarians throughout the United States shortly thereafter.
- 16. In accordance with applicable laws, Putney commercially launched a generic human-approved form of cefpodoxime proxetil tablets, 100 mg and 200 mg, at the end of March 2007, and currently sells such products to veterinary practices and distributors (the "Putney Product").

Putney's and MWI's arrangement for the distribution of the Putney Product

17. In or about late October 2006 or early November 2006, Putney and MWI commenced discussions concerning MWI serving as the only distributor of the Putney Product with a national and outside sales force, in part because of MWI's experience with selling and distributing FDA human approved products to the veterinary community and related knowledge of applicable FDA rules and regulations concerning the sale and distribution of such products.

When these discussions commenced, Putney advised MWI that its cefpodoxime product was a human-approved product that would be sold to the veterinary community, and that in light of these circumstances, Putney could not advertise or promote such product under AMDUCA.

- November 2006. Putney and MWI entered into the Distribution Agreement dated December 1, 2006 (the "Distribution Agreement"), wherein MWI agreed, *inter alia*, to sell and distribute the Putney Product to veterinarians throughout the United States. It was the parties' understanding and intent that the Distribution Agreement did not concern or govern sales between Putney and Banfield, The Pet Hospital, a corporate vet practice. A true and correct copy of the Distribution Agreement is attached hereto as Exhibit A.
- 19. The term of the Distribution Agreement is from January 1, 2007, to and including December 31, 2007.
- 20. The Distribution Agreement contains a confidentiality provision, which, *inter alia*, prohibits MWI from disclosing "confidential information" and the terms of the Distribution Agreement to any third party.
- 21. After discussion and consideration, it ultimately was the parties' understanding and agreement that MWI would serve as the only distributor of the Putney Product with a national and outside sales force.
- 22. MWI formally advised Putney on September 8, 2007, that it would not renew the Distribution Agreement with Putney for the sale and distribution of the Putney Product, upon the effective end date of that Agreement, December 31, 2007.

Pfizer's communications with MWI

- 23. Upon information and belief, in the first half of 2007, Pfizer became aware that MWI was distributing the Putney Product. Also upon information and belief, in the first half of 2007, Pfizer and MWI had discussions, either directly or indirectly, regarding MWI's distribution arrangement with Putney for the Putney Product.
- 24. Upon information and belief, upon learning of MWI's distributing arrangement with Putney, Pfizer notified MWI, either directly or indirectly, that (i) Putney was purportedly engaged in the "illegal" promotion and sale of the Putney Product in violation of Pfizer's exclusive rights with respect to the cefpodoxime proxetil approved for animal use in the United States; and (ii) Pfizer would curtail Pfizer's business relationship with MWI unless MWI stopped distributing the Putney Product.

MWI's conduct following communications with Pfizer

- 25. Putney has received information that MWI informed customers (both existing and potential) and others that (i) MWI was no longer selling the Putney Product, and (ii) there were purported regulatory issues with the Putney Product.
- 26. On or about April 26, 2007, MWI instructed its sales force that "[e]ffective immediately and until further notice, MWI will stop offering Putney's Cefpodoxime Proxetil Tablets. This change is not related to any product quality concerns, but is rather the result of our own review of certain regulatory issues for distributors." It is Putney's understanding that these instructions and/or representations by MWI were a direct result of conversations that occurred between Pfizer and MWI, in which Pfizer notified MWI, among other things, that (i) Putney was purportedly engaged in the "illegal" promotion and sale of the Putney Product in violation of Pfizer's exclusive rights with respect to the cefpodoxime proxetil approved for animal use in the

United States; and (ii) Pfizer would curtail Pfizer's business relationship with MWI unless MWI stopped distributing the Putney Product.

- 27. During and following the negotiation and execution of the Distribution Agreement, MWI never advised or suggested to Putney that it would not serve as Putney's nationwide distributor of the Putney Product because that Product was a human-approved product that would be sold to the veterinary community under AMDUCA. Rather, MWI assured Putney that it had experience with and significant ongoing business concerning the selling and distributing of FDA human approved products to the veterinary community, in addition to knowledge of applicable FDA rules and regulations concerning the sale and distribution of such products, and as such, was capable of serving as Putney's distributor.
- 28. MWI only first raised concerns over Putney's sale and/or MWI's distribution of the Putney Product, including that such sales purportedly violated federal law, that ultimately resulted in MWI advising that it would not serve as Putney's distributor subsequent to Pfizer's communications with MWI that, among other things, (i) Putney was purportedly engaged in the "illegal" promotion and sale of the Putney Product in violation of Pfizer's exclusive rights with respect to the cefpodoxime proxetil approved for animal use in the United States; and (ii) that Pfizer would curtail Pfizer's business relationship with MWI unless MWI stopped distributing the Putney Product.
- 29. Thereafter, on April 30, 2007, John Ryan, the Vice President of Marketing for MWI, corresponded with MWI's Sales Representatives and stated that "[w]e have heard of isolated reports of vets being confused as to the reason for Putney's Cefpodoxime Proxetil being no longer available for MWI. It seems that some might believe that the product is on a recall (it is not on recall)."

30. On May 14, 2007, MWI notified Putney, in writing, of its intent to stop distributing the Putney Product to any existing or potential customers other than one customer (Banfield). A true and correct copy of the May 14, 2007 letter from MWI to Putney is attached hereto as Exhibit B.

Pfizer's threat letter

- 31. On or about May 29, 2007, Pfizer, through its counsel (Dechert LLP), contacted Putney by letter, in which Pfizer, *inter alia*, threatened to seek injunctive relief and other remedies against Putney arising from Pfizer's purported rights with respect to Simplicef[®]. A true and correct copy of the May 29, 2007 letter from Pfizer to Putney is attached as <u>Exhibit C</u>.
 - 32. Upon information, MWI is also represented by Dechert LLP.

Pfizer's communications with the veterinary industry concerning Putney and the Putney Product

33. Subsequent to MWI's decision in or about May 2007 to no longer sell the Putney Product, Putney pursued and/or focused on relationships with other distributors, including Amatheon and Tri V Services, for the distribution of the Putney Product. Certain of the distributors with which Putney entered into agreements to sell and distribute the Putney Product, including Amatheon and Tri V Services, are no longer distributing the Putney Product and/or ceased purchasing the Product from Putney. On information and belief, the relationship between Putney and these distributors terminated as a result of, either directly or indirectly, Pfizer's disparaging comments about the Putney Product and Pfizer's successful efforts to instill fear in the veterinary community concerning the Putney Product, including that the sale and/or distribution of such Product would violate Pfizer's exclusivity or other regulations of FDA and that there were regulatory or other issues with the Product.

- 34. On information and belief, Pfizer, including through its sales representatives, currently is communicating to veterinarians throughout the United States, orally and/or in writing, that the Putney Product is being "pulled" from the market and that the sale and/or distribution of such Product would violate Pfizer's exclusivity or other regulations of FDA and that there are regulatory or other issues with the Product.
- 35. On information and belief, Pfizer is communicating to distributors of veterinary pharmaceutical products throughout the United States, orally and/or in writing, that Putney is illegally promoting the Putney Product as "generic Simplicef"; that the sale and/or distribution of such Product would violate Pfizer's exclusivity or other regulations of FDA; and/or that there are regulatory or other issues with the Product. Such communications include a written letter distributed by Pfizer in September 2007, to, among others, various distributors of veterinary pharmaceutical products throughout the United States.
- 36. On information and belief, Pfizer is communicating such information negligently or with reckless disregard of the truth or accuracy of such information in a direct effort to eliminate competition by Putney and/or to injure Putney's business and reputation in the veterinary pharmaceutical industry. Such conduct is particularly harmful to Putney as a small, start-up pharmaceutical company.

COUNT I (Declaratory Judgment Against Pfizer and MWI under Lanham Act)

- 37. Putney repeats and realleges Paragraphs 1 through 36 as if fully set forth herein.
- 38. There is an actual, substantial, and continuing justiciable case or controversy among Pfizer, MWI and Putney regarding whether Putney has engaged in unfair trade practices, unfair competition and/or any other improper conduct subject to redress under the Lanham Act and other applicable laws in connection with the Putney Product.

- 39. In a letter dated May 29, 2007, Pfizer accused Putney of, *inter alia*, "creating the false and misleading impression in the marketplace that Putney's promotion and sale of cefpodoxime proxetil . . . has been approved by the FDA and is otherwise in accordance with law. These actions, as well as your willful violation of federal law, constitute unfair trade practices and unfair competition subject to redress under the Lanham Act and other applicable laws."
- 40. Pfizer has threatened to seek injunctive relief and other remedies against Putney for these alleged acts.
- 41. On information and belief, MWI, after communications with Pfizer, ceased performing under the Distribution Agreement purportedly based upon similar wrongful acts.
- 42. Putney is not engaging, nor has it engaged, in unfair trade practices, unfair competition or any other act in connection with the Putney Product that would violate federal, state or common law.
- 43. Putney is entitled to a judicial declaration that its actions have not and do not violate the Lanham Act or any other applicable federal, state or common law.

WHEREFORE, Putney, Inc. requests that this Court enter judgment in its favor and against Defendants Pfizer Inc. and MWI Veterinary Supply, Inc. as to Count I of the Complaint, declaring that Putney's actions have not and do not violate the Lanham Act or any other applicable federal, state or common law.

COUNT II (Declaratory Judgment Against Pfizer and MWI under AMDUCA)

44. Putney repeats and realleges Paragraphs 1 through 43 as if fully set forth herein.

- 45. There is an actual, substantial, and continuing justiciable case or controversy among Pfizer, MWI and Putney regarding whether Putney has engaged in conduct illegal under AMDUCA in connection with the Putney Product.
- 46. In a letter dated May 29, 2007, Pfizer stated, *inter alia*, that "Putney promotes all of its generic drugs for use with animals. In the case of cefpodoxime proxetil, this conduct is illegal." Pfizer further asserts that Putney's "interpretation of AMDUCA is misleading and wrong. AMDUCA allows veterinarians to use approved human drugs for extra-label use in animals under certain conditions. It expressly does not allow unapproved manufacturers or distributors to promote or advertise the drug for extra-label use in animals which is exactly what Putney is doing."
- 47. Pfizer has threatened to seek injunctive relief and other remedies against Putney for these alleged acts.
- 48. On information and belief, MWI, after communications with Pfizer, has ceased performing under the Distribution Agreement purportedly based upon similar wrongful acts.
- 49. Putney is not engaging, nor has it engaged, in conduct in connection with the Putney Product that would violate federal, state or common law, including AMDUCA.
- 50. Putney is entitled to a judicial declaration that its actions have not and do not violate AMDUCA.

WHEREFORE, Putney, Inc. requests that this Court enter judgment in its favor and against Defendants Pfizer Inc. and MWI Veterinary Supply, Inc. as to Count II of the Complaint, declaring that Putney's actions have not and do not violate AMDUCA.

COUNT III (<u>Deceptive Trade Practices – 10 M.R.S.A. 1211 et seq. – Against Pfizer</u>)

51. Putney repeats and realleges Paragraphs 1 through 50 as if fully set forth herein.

- 52. By falsely representing to MWI that Putney was engaged in the "illegal" promotion of the Putney Product in violation of Pfizer's rights as to cefpodoxime proxetil in the United States, Pfizer willfully disparaged the goods, services or business of Putney in violation of Maine's Uniform Deceptive Trade Practices Act.
- 53. Upon information and belief, Pfizer made these misrepresentations to MWI to gain a competitive advantage in the veterinary pharmaceutical market by pressuring MWI to refuse to distribute the Putney Product, thereby hindering and/or blocking Putney's ability to compete in the veterinary pharmaceutical marketplace.
- 54. Putney has been irreparably damaged and is likely to continue to be irreparably damaged by Pfizer's violation of Maine's Uniform Deceptive Trade Practices Act.

WHEREFORE, Putney, Inc., requests that this Court grant injunctive relief in its favor and against Defendant Pfizer Inc. as to Count III of the Complaint, enjoining Pfizer Inc. from making misrepresentations or otherwise disparaging the Putney Product, and grant Putney reasonable attorney's fees.

COUNT IV (<u>Deceptive Trade Practices – 10 M.R.S.A. 1211 et seq. – Against MWI</u>)

- 55. Putney repeats and realleges Paragraphs 1 through 54 as if fully set forth herein.
- 56. MWI falsely represented to Customers that the Putney Product had regulatory issues and MWI therefore ceased selling the Putney Product thereby willfully disparaging the goods, services or business of Putney in violation of Maine's Uniform Deceptive Trade Practices Act.
- 57. Putney has been irreparably damaged and is likely to continue to be irreparably damaged by MWI's violation of Maine's Uniform Deceptive Trade Practices Act.

WHEREFORE, Putney, Inc., requests that this Court grant injunctive relief in its favor and against Defendant MWI Veterinary Supply, Inc. as to Count IV of the Complaint, enjoining MWI from making misrepresentations or otherwise disparaging the Putney Product, and grant Putney reasonable attorney's fees.

COUNT V (Tortious Interference with Contract – Against Pfizer)

- 58. Putney repeats and realleges Paragraphs 1 through 57 as if fully set forth herein.
- 59. By fraud or intimidation (by threatening to curtail Pfizer's business relationship with MWI unless MWI stopped distributing the Putney Product), Pfizer induced MWI to breach the Distribution Agreement.
- 60. MWI would have continued to perform its obligations under the Distribution Agreement but for the fraud or intimidation exercised by Pfizer over MWI.
- 61. As a result of Pfizer's tortious interference with the Distribution Agreement, Putney has sustained and will continue to sustain damages in an amount to be proven at trial.

WHEREFORE, Putney, Inc., requests that this Court enter judgment in its favor and against Defendant Pfizer Inc. as to Count V of the Complaint, and enter an award of damages in favor of Putney.

COUNT VI

(<u>Tortious Interference with Contract and/or Advantageous Relationship – Against Pfizer</u>)

- 62. Putney repeats and realleges Paragraphs 1 through 61 as if fully set forth herein.
- 63. Through fraud, fear and/or intimidation, Pfizer caused distributors, such as Amatheon and Tri V Services, either directly or indirectly to cease distributing and purchasing from Putney the Putney Product and therefore to terminate their respective distributing arrangements with Putney.

- 64. These distributors would have continued to perform their respective obligations with Putney but for the fraud, fear or intimidation exercised by Pfizer over the distributors.
- 65. As a result of Pfizer's tortious conduct, distributors such as Amatheon and Tri V Services ceased their distributing relationship with Putney for the Putney Product; as a result, Putney has sustained and will continue to sustain damages in an amount to be proven at trial.

WHEREFORE, Putney, Inc., requests that this Court enter judgment in its favor and against Defendant Pfizer Inc. as to Count VI of the Complaint, and enter an award of damages in favor of Putney.

COUNT VII (Defamation – Against Pfizer)

- 66. Putney repeats and realleges Paragraphs 1 through 65 as if fully set forth herein.
- 67. Pfizer has been communicating false and defamatory statements, in writing and/or orally, concerning Putney and the Putney Product to third parties, including veterinarians, distributors of the Putney Product, distributors of veterinary pharmaceutical products and other employees involved with the purchase of veterinary drug products at veterinary practices, all throughout the United States. Such statements include that Putney is illegally promoting the Putney Product as "generic Simplicef"; that the sale and/or distribution of such Product would violate Pfizer's exclusivity or other regulations of FDA; that there are regulatory or other issues with the Product; and/or that the product will be "pulled" from the market; the statements further concern the quality of the Putney Product, such as that the Putney Product is substandard to Simplicef[®].
 - 68. The statements to these third parties are not privileged.
- 69. Pfizer, through at least negligence or reckless disregard, caused such false and defamatory statements to be communicated to these third parties in an effort to harm Putney's

business, and has otherwise negligently or recklessly communicated such statements without determining the validity or accuracy of such information, which is in fact false.

- 70. As a result of Pfizer's false and defamatory statements, Putney has incurred economic and pecuniary injury, in the form of lost sales and business opportunities (including opportunities for future business and products) from third parties to whom Pfizer has communicated its false and defamatory statements, which opportunities are vital to a new company such as Putney. Putney also has suffered a loss of reputation as a provider of safe, effective pharmaceutical products for the veterinary community, which has resulted in a loss of material advantages, particularly since Putney is a small, new start-up company. As such, Pfizer's statements are actionable and/or special harm exists that was caused by Pfizer's statements.
- 71. WHEREFORE, Putney, Inc., requests that this Court grant injunctive relief and enter judgment in its favor and against Defendant Pfizer Inc. as to Count VII of the Complaint, enjoining Pfizer Inc. from making misrepresentations and/or false and defamatory statements about Putney and the Putney Product, and enter an award of damages in favor of Putney.

COUNT VIII (<u>Breach of Contract – Against MWI</u>)

- 72. Putney repeats and realleges paragraphs 1 through 71 as if fully set forth herein.
- 73. Pursuant to the Distribution Agreement, MWI was required to distribute the Putney Product to veterinarians throughout the United States.
- 74. By refusing to distribute the Putney Product to any customers other than Banfield, MWI has breached the Distribution Agreement.
- 75. As a result of this breach of the Distribution Agreement by MWI, Putney has been damaged in an amount to be proven at trial.

- 76. Likewise, by directly or indirectly disclosing the business arrangement contained in the terms of the Distribution Agreement to Pfizer, MWI is in breach thereof.
- 77. As a result of these breaches of the Distribution Agreement by MWI, Putney has been damaged in an amount to be proven at trial.

WHEREFORE, Putney, Inc., requests that this Court enter judgment in its favor and against Defendant MWI Veterinary Supply, Inc. as to Count VIII of the Complaint, and enter an award of damages in favor of Putney.

COUNT IX (Indemnification – Against MWI)

- 78. Putney repeats and realleges Paragraphs 1 through 77 as if fully set forth herein.
- 79. The Distribution Agreement requires MWI to indemnify Putney for all losses, damages, or expenses, including its attorneys' fees, incurred in connection with this lawsuit.

WHEREFORE, Putney, Inc., requests that this Court enter judgment in its favor and against Defendant MWI Veterinary Supply, Inc. as to Count IX of the Complaint, and enter an award of damages in favor of Putney.

COUNT X (Promissory Estoppel – Against MWI)

- 80. Putney repeats and realleges Paragraphs 1 through 79 as if fully set forth herein.
- 81. MWI made a clear and unambiguous promise to Putney, both expressly and through its conduct, that MWI would serve as the only distributor of the Putney Product with a national and outside sales force and that any distribution contemplated by the distribution arrangement between MWI and Putney would be separate and apart from any distribution of the Product to Banfield.

82. MWI understood and intended, or reasonably should have understood and

intended, that Putney would reasonably rely to its detriment on MWI's promise and not pursue

relationships or arrangements with other distributors with a national and outside sales force for

the launch, sale and distribution of the Putney Product.

83. Putney in fact, and in good faith, did reasonably rely to its ultimate detriment on

MWI's promise and did not pursue any such relationships or agreements for the launch, sale and

distribution of the Putney Product. Such reliance was reasonable and foreseeable under the

circumstances.

84. Putney suffered damages, in an amount to be determined at trial, as a direct and

proximate result of it reasonable reliance on MWI's promise and related conduct.

85. Under such circumstances, an injustice will result if MWI is not bound by its

promise and/or representations.

WHEREFORE, Putney, Inc., requests that this Court enter judgment in its favor and

against Defendant MWI Veterinary Supply, Inc. as to Count X of the Complaint, and enter an

award of damages in favor of Putney.

JURY DEMAND

The Plaintiff, Putney, Inc., hereby demands a trial by jury on all issues so triable.

Dated at Portland, Maine, this 3rd day of January, 2008.

/s/ John A. Ciraldo, Esq.

John A. Ciraldo, Esq.

/s/ Jennifer H. Pincus, Esq.

Jennifer H. Pincus, Esq.

Attorneys for Plaintiff, Putney, Inc.

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CERTIFICATE OF SERVICE

I hereby certify that on 3rd day of January, 2008, I electronically filed the foregoing First Amended Complaint for Damages, Declaratory Judgment, and Injunctive Relief with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record in this action. I also have mailed by United States Postal Service, the document to all counsel of record in this action.

/s/ Jennifer H. Pincus, Esq.
Jennifer H. Pincus, Esq.
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